REMARKS

Upon entry of the amendments presented, Claims 1 and 14 have been amended to more specifically characterize the range of tabletting pressures for use in making the infant formula tablets, such that the resulting infant formula tablet does not contain a fatty or oily film on the exterior of the tablet. Support for this amendment can be found in Applicants' specification, for example, at page 3, lines 2-6, and at page 12, lines 15-19.

Also upon entry of the amendments presented, Claims 1 and 14 have been amended to characterize the dissolution test methods (manual, mechanical) which help define the dissolution characteristics of the claimed infant formula tablets. Support for this amendment can be found in Applicants' specification, for example, at page 3, lines 28-36, and at page 4, lines 1-33.

Also upon entry of the amendments presented, Claims 12, 13, and 15 have been cancelled, without prejudice. Claims 1-11 and 14 remain pending in the application.

Invention Synopsis

The present invention is directed to infant formula tablets suitable for reconstitution with water to form an infant formula liquid. The tablets comprise from 10% to 20% by weight of protein, from 40 to 70 % by weight of carbohydrate, and at least about 20% by weight of fat, wherein the reconstitutable tablet is formed under a pressure selected from a range of with from about 400 psi to about 1500 psi, and wherein the pressure is selected so that a film of fat does not form on the exterior tablet surface, and wherein the resulting infant formula tablet dissolves within 60 seconds in accordance with a manual dissolution test.

It has been found that a reconstitutable infant formula tablet having a relatively high fat content can be manufactured which is physically durable during storage *and* which also rapidly dissolves in water within 60 seconds to form a ready to feed infant formula liquid. In particular, it was found that the tablets could be formulated to dissolve rapidly prior to use, despite the relatively high fat content, provided that the tabletting pressure is selected from a range of from about 400 psi to about 1500 psi, wherein the pressure for any particular tablet form is carefully selected to avoid the formation of a fatty or oily film on the exterior surface of the tablet. If the selected pressure is too high, a fatty or oily film will form around the tablet, which will then prevent rapid tablet dissolution.

Technical Matters

Claims 1-15 have been rejected under 35 USC 112, second paragraph, as being indefinite for reciting a dissolution method that referenced Applicants' specification. Responsive to this rejection, Claims 1 and 14 have been amended to recite the appropriate test methods as defined in Applicants' specification.

Applicants respectfully submit that remaining Claims 1-11 and 14 as currently amended are now in complete compliance with the definiteness requirements of 35 USC 112. This rejection should, therefore, be withdrawn.

Art Rejection

Claims 1-15 have been rejected under 35 USC 103 as unpatentable over Brochner (GB 894,001) in view of Ozalvo et al. (WO 03/077664 A1). The USPTO contends that it would have been obvious to prepare a baby formula tablet as disclosed by Ozalvo et al. with the nutrient concentrations disclosed by Brochner, to thereby realize Applicants' invention. Applicants respectfully traverse this rejection as it would apply to the amended claims.

Brochner discloses milk tablets for use and dissolution in warm aqueous liquids such as coffee, tea, and cocoa. The tablets comprise 10-29% butter fat, 7-15% milk protein, 15-65% carbohydrates and other minor ingredients and water (see Brochner, page 1, lines 84-88). Brochner teaches the manufacture of a readily soluble milk tablet formed by the compression of powdered milk (SEE Brochner, page 1, lines 51-65).

Ozalvo et al. discloses reconstitutable tablets for use in preparing an infant formula prior to feeding. The tablets are preferably fast dissolving, which is accomplished according to Ozalvo et al. by designing different tablet shapes to have a larger surface to volume ratio (see Ozalvo et al., page 6, lines 5-9).

Neither reference, taken alone or in combination, discloses or suggests that tablet dissolution can be greatly improved upon by controlling tabletting pressure. Ozalvo et al. teaches that table dissolution can be improved by increasing the tablet surface area to volume ratio. Brochner is silent as to how to improve tablet dissolution.

Applicants have found that tablet dissolution rates are dramatically and undesirably slowed if the tabletting pressures are allowed to reach a threshold at or above which a fatty or oily film forms on the exterior surface of the tablets. Applicants have found that these infant formulas containing relatively high fat concentrations are especially susceptible to this problem. Ozalvo et al. and Brochner are completely silent as this particular problem.

Applicants have now amended Claims 1 and 14 to further emphasize the range of tabletting pressures that are appropriate for making a rapidly dissolving infant formula tablet. Applicants have also amended these same claims to emphasize selection of only those tabletting pressures for any particular tablet form that *do not* result in the formation of a fatty or oily film on the exterior surface of the tablet. Neither Ozalvo et al. nor Brochner suggest such limitations

Moreover, the only tableting pressure suggested by either applied prior art reference was that noted by Ozalvo et al. at page 11, lines 3-6 (0.25 tons applied to a 2 gm tablet). It is unclear from the description exactly what pressure was actually applied (i.e., psi value) to the Ozalvo et al. tablet, since such pressures can be affected by factors such as the topical area of the tablet form as well as the configuration or size of the tablet punch used in the press. Ozalvo et al., of course, made no provision whatsoever for controlling or adjusting such pressures for any purpose, and certainly didn't suggest any such control or adjusting to avoid the formation of a fatty or oily film on the tablet surface (which would then slow down tablet dissolution rates).

In short, the applied references together fail to disclose or suggest the dissolution problem that arises with these reconstitutable tablets when a fatty or oily film is unknowingly formed around the tablet due to excessive tabletting pressures. And neither reference, of course, suggests any solution to such a problem, let alone the solution suggested by Applicants for the present invention by selection of tabletting pressures to avoid development of an exterior fatty or oily film.

In view of the amendments presented and the foregoing remarks, Applicants respectfully submit that a rejection of Claims 1-11 and 14 as unpatentably obvious over Brochner in view of Ozalvo et al. would now be improper. This rejection should, therefore, be withdrawn.

Conclusion

Applicants have made an earnest effort to place their application in proper form and to distinguish their claimed invention from the applied prior art. WHEREFORE, reconsideration of this application, withdrawal of the rejections under 35 USC 103 and 35 USC 112, second paragraph, and early allowance of all claims are respectfully requested.

Respectfully submitted,

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